

REMARKS

Claims 1-11 and 14-22 are pending in the instant application. Claims 1, 6-11 and 17 are rejected. Claims 2, 4, 7 and 11 are objected to. Claims 14-16 and 18-22 are withdrawn from consideration.

Regarding Restriction Requirement and Election of Species Requirement

The Examiner indicates that restriction and election were proper and only examines claims 1-11 and 17 on the merits.

Objection to the Specification

The Examiner objects to the specification because it contains a hyperlink. Applicant herein deletes the hyperlinks in each occurrence.

Objection to the Claims

The Examiner objects to claim 2 as broader than claim 1. The Examiner further objects to claims 4, 7 and 11 for using the term “CCA1” without spelling out what is meant by the acronym. Applicant herein solely to expedite prosecution, cancels claims 2, 4, 7 and 11. Thus, the objections are moot.

Rejection under 35 U.S.C. 101

The Examiner rejects claim 11 as drawn to unpatentable subject matter because it does not recite “isolated and purified” to describe the CCA1. Applicant herein deletes the offending claim 11 purely in the interest of expediting prosecution.

Rejection under 35 U.S.C. 112, first paragraph

As regards Written Description

The Examiner rejects claims 2 and 7 as not properly described because of the language “wherein the CCA1 comprises a fragment, a function-conservative variant, an active fragment or

a fusion protein of CCA1.” Applicant herein deletes the offending claims 2 and 7 purely in the interest of expediting prosecution.

The Examiner rejects claims 9, 10, 11 and 17 as not properly described because they are “reach through” claims that embrace compounds identified by a screening method. Applicant herein deletes the offending claims 9, 10, 11 and 17 purely in the interest of expediting prosecution. Applicant, however, respectfully submits that the patent law does not require any number of species to describe a genus.

As regards Enablement

The Examiner rejects claims 1-3, 8-11 and 17 as not properly enabled. The Examiner maintains that

1. interaction of a compound with CCA1 does not predict its activity as an antifungal agent;
2. the specification does not provide guidance on how interaction of a compound with CCA1 is assessed by the growth or viability of cells expressing fungal CCA1 and how this relates to impairment of CCA1; and
3. the specification does not provide any working examples of a compound identified by the screening methods that interacts with CCA1 and impairs CCA1 activity and it is unpredictable whether any compound that interacts with CCA1 may also act as an antifungal.

Applicant reminds the Examiner that the legal test for whether a patent application complies with the requirements of 35 USC 112, first paragraph as regards enablement is whether one of ordinary skill in the art would be able to practice the invention as presently claimed without undue experimentation. Applicant respectfully further reiterates that according to the court of *In re: Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the legal standard is that enablement is not precluded by the necessity for some experimentation such as routine screening.

Applicant herein changes claim 1 to recite that the CCA1 protein is from the species *Candida albicans*. No issue of new matter arises by way of this change as express support for this recitation can be found in claim 3 as filed. Accordingly, claim 3 is canceled. Further, claims 2 and 10 are canceled without prejudice.

Applicant further changes claims 1 and 8 to define the term "function" as "activity." No issue of new matter arises by way of this change as express support can be found in paragraph [0020]. Further, claim 8 is amended to indicate that the effect of a compound on the activity of CCA1 is determined by comparison with a sample in which the promoter is repressed such that the CCA1 gene is not expressed in the presence or absence of a candidate compound. One of ordinary skill in the art would readily understand that because the instant invention is based, at least in part, upon the discovery that CCA1 in *Candida albicans* is essential for viability of the yeast (*See, e.g.* Example 4), a compound that impairs CCA1 activity in such an assay effects the viability of the yeast, i.e. displays an anti-fungal effect. Support for these amendments can be found in paragraphs [0040], [0041], [0100] and [0101]. Practicing the instant methods constitutes no more than the routine screening specifically sanctioned by the law, as set forth, *supra*.

Rejection under 35 U.S.C. 112, second paragraph

The Examiner rejects claims 2-3, 9, and 17 as unclear. The Examiner suggests that since these are dependent claims, the "A" should be changed to "the" to refer to the independent claims from which they depend. Applicant herein deletes the offending claims 2-3, 9, and 17 purely in the interest of expediting prosecution.

Rejection under 35 U.S.C. 102

The Examiner rejects claims 1-2 and 9 as allegedly anticipated by Sternbach *et al.*, 1976, *Eur. J. Biochem.* 67:215-221. Applicant submits that Sternbach *et al.* disclose an assay for CCA1 from Baker's yeast. Sternbach *et al.* do not teach or suggest an assay for CCA1 from *Candida albicans*. Thus, Sternbach *et al.* do not anticipate claim 1 as amended, and claims 2 and 9 are

deleted.

The Examiner rejects claims 1-2 and 8 as allegedly anticipated by Bradley *et al.*, WO 02/02784A1. As noted, *supra*, claim 1 is herein amended to specify that the fungal CCA1 is from the *Candida* species. Bradley (WQ02/02784) discloses yeast strains having genes whose expression can be modulated by growth in the presence or absence of metal ions. However, these yeast strains are restricted to strains of *Saccharomyces cerevisiae* (See, e.g. page 2, line 12; page 3, line 25 and, in particular, page 12, line 14-16; and all the Examples). Bradley only teaches *Saccharomyces cerevisiae* cells. Bradley does not teach or suggest CCA1 from the *Candida* species, hence, Bradley does not teach or suggest the invention as currently described in claims 1 or 8 as amended. Claim 2 is herein canceled.

The Examiner rejects claims 1-2 and 9 as allegedly anticipated by Kroger *et al.*, 1979, *Eur. J. Biochem.* 95:341-348. As noted, *supra*, claim 1 is herein amended to specify that the fungal CCA1 is from the *Candida* species. Kroger *et al* disclose an assay for CCA1 from Baker's yeast. Kroger *et al.* do not teach or suggest CCA1 from *Candida albicans*.

The Examiner rejects claims 1-2, 9 and 10 as allegedly anticipated by Navarro *et al.*, 1991, *Italian J. Biochem.* 40(5):295-303. As noted, *supra*, claim 1 is herein amended to specify that the fungal CCA1 is from the *Candida* species. Navarro *et al.* disclose an assay for CCA1 from *Saccharomyces cerevisiae*. Navarro *et al.* do not teach or suggest CCA1 from *Candida albicans*. Thus, Navarro *et al.* do not anticipate claim 1 as amended. Because claims 2, 9 and 10 are herein deleted, the Examiner's rejection is moot.

The Examiner rejects claims 4 and 7 as allegedly anticipated by Deng *et al.*, 2000, *Yeast* 16: 945-952. The Examiner rejects claims 4, 6 and 7 as allegedly anticipated by Wolfe *et al.*, 1996, *J. Biol. Chem.* 271: 4679-4686. The Examiner rejects claims 4, 6, 7 and 11 as allegedly anticipated by Hanic-Joyce *et al.*, 2002, *Yeast* 19: 1399-1411. The Examiner rejects claims 4, 6 and 7 as allegedly anticipated by Chen *et al.*, 1992, *J. Biol. Chem.* 267: 14879-14883. The Examiner rejects claims 4, 6 and 7 as allegedly anticipated by Aebi *et al.*, 1990, *J. Biol. Chem.* 265: 16216-16220. Purely in the interest of advancing

prosecution, and as set forth, *supra*, Applicant herein cancels claims 4, 6, 7 and 11 thereby obviating the rejection. Applicant notes that claims 3, 5 and 8 are apparently acknowledged as patentable over the prior art.

Rejection under 35 U.S.C. 103

The Examiner rejects claims 4, 6 and 7 as allegedly unpatentable over Hanic-Joyce *et al.*, 2002, *Yeast* 19: 1399-1411 in view of Backen *et al.*, *Yeast*, 2000, 16:1121-1129. The Examiner admits that Hanic-Joyce *et al.* do not teach a modified *Candida albicans* expressing fungal CCA1 under the control of a heterologous promoter. However, the Examiner says that it would have been *prima facie* obvious to express the fungal CCA1 in *C. albicans* as taught by Backen *et al.* resulting in the instant invention because the heterologous promoter of Backen *et al.* provides a useful means for functional analysis of genes in *C. albicans*.

The Examiner rejects claims 2 and 7 as allegedly unpatentable over Wolfe *et al.*, 1996, *J. Biol. Chem.* 271: 4679-4686 in view of Invitrogen Catalog, 2000, page vii and page 79. The Examiner admits that Wolfe *et al.* do not teach a modified eukaryotic cell expressing a fusion protein of CCA1 under the control of a heterologous promoter. However, the Examiner says that it would have been *prima facie* obvious to transform the *S. cerevisiae* of Wolfe *et al.* with any of the N- or C-terminal tagged plasmids of Invitrogen having CCA1 under the control of a heterologous promoter because the tags on the fusion protein allow for convenient detection and purification.

As described, *supra*, and purely in the interest of advancing prosecution and securing rapid issuance of a patent, Applicant herein cancels claims 2, 4, 6, and 7 thereby obviating the rejection.

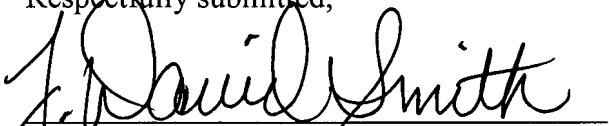
Fees

No fees are believed to be necessary in connection with this response. However, if this is in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

Conclusion

Applicant believes that the foregoing amendments to the claims place the application in condition for allowance. Withdrawal of the rejections is respectfully requested. If a discussion with the undersigned will be of assistance in resolving any remaining issues, the Examiner is invited to telephone the undersigned at (201) 487-5800, ext. 114, to effect a resolution.

Respectfully submitted,



J DAVID SMITH
Attorney for Applicant(s)
Registration No. 39,839

KLAUBER & JACKSON, LLC
411 Hackensack Avenue, 4th Floor
Hackensack, NJ 07601
(201) 487-5800